

8-18-00

A

Please type a plus sign (+) inside this box --> ☐PTO/SB/05 (4/98)
Approved for use through 09/30/2000. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

UTILITY
PATENT APPLICATION
TRANSMITTAL

Only for new nonprovisional applications under 37 C.F.R. § 1.53(b)

Attorney Docket No. PA036
First Inventor or Application Identifier William Kanz
Title Supplemental Port for Catheter Perfusion of Surgical Site
Express Mail Label No. EL514049135US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington DC 20231

1. ☒ Fee Transmittal Form (e.g. PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Specification [Total Pages 19]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure
3. ☒ Drawing(s) (35U.S.C. 113) [Total Sheets 4]
I
4. Oath or Declaration [Total Pages 23]
I
- a. ☒ Newly executed (original or copy)
- b. ☐ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
- ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting
inventor(s) named in the prior application,
see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

5. ☐ Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
- a. ☐ Computer Readable Copy
- b. ☐ Paper Copy (identical to computer copy)
- c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. ☐ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement of Power of Attorney
(when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☐ Information Disclosure Statement (IDS)/PTO-1449 [Copies of IDS Citations]
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
- Small Entity
13. ☐ Statement(s) filed in prior application, Status still proper and desired
(PTO/SB/09-12)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other:

* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY
FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT
IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28)

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment-

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No. 09 / 313,268
Prior application Information - Examiner Patricia Bianco Group I Art Unit- 3762

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

☒ Customer Number or Bar Code Labelor ☐ Correspondence address below

Name	Jonathan Spangler, Esq.				
Address	A-Med Systems, Inc. 2491 Boatman Avenue				
City	West Sacramento	State	California	Zip Code	95691
Country	US	Telephone	(916) 375-7400, Ext. 301	Fax	(916) 375-7444

Name (Print/Type)	Jonathan Spangler, Esq.	Registration No (Attorney/Agent)	40,182
Signature		Date	August 16, 2000

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

SUPPLEMENTAL PORT FOR CATHETER PERFUSION OF SURGICAL SITE

BACKGROUND OF THE INVENTION

I. Field of the Invention

5 The present invention relates generally to blood
pumps for use during heart surgery. More
specifically, the present invention involves
providing a supplemental port on a blood pump for
10 delivering blood to a surgical site via a catheter or
cannula arrangement to perfuse the tissue downstream
from the surgical site.

II. Discussion of the Prior Art

15 During open heart surgery and in some emergency
cardiopulmonary situations, it is necessary to have
some means to bypass the heart with a blood pump.
The bypass circuit may be used to completely replace
the function of the heart or it may be employed to
20 assist the heart. Typically in a bypass circuit, an
inflow cannula is placed within the left ventricle
and an outflow cannula is placed within the aorta.
Bypass surgery typically is used to repair damaged or
occluded vessels on the heart. To repair a vessel or
25 occlusion, the surgeon usually will graft a new
vessel that will supply blood to the affected area.
Before applying the graft, the surgeon will occlude
the target vessel proximally to the damaged area.

One problem with doing this is that healthy tissue beyond or downstream from the damaged area no longer receives sufficient blood or oxygen during the operation.

5 Typically, such a circuit will be used for cardiopulmonary arterial bypass graph (CABG) surgery to support or supplement the heart. While CABG surgery may be accomplished on a beating heart or a still heart, the trend is moving towards beating
10 heart surgery because it is less traumatic to the patient. When conducting beating heart CABG surgery, the patient's vessels and arteries require a replenished flow of oxygenated blood in order for the tissues to sustain without damage. When the surgeon
15 is performing an anastomosis, the target vessel is occluded proximally to the surgical site. Problems associated with occluding the vessel include damage to tissue distal the anastomosis site. In extreme cases, the patient will require a second surgery to
20 correct complications that were created by the first surgery.

The present invention is directed at overcoming, or at least reducing the effects of, one or more of the problems set forth above.

25

SUMMARY OF THE INVENTION

The present invention concerns a blood pump with a supplemental outflow port(s). A catheter can be attached to the supplemental port at a proximal end, while the distal end of the catheter may be placed where it is desired to have a supplemental blood flow.

During CABG surgery, typically one or more of the patient's vessels are occluded. Once the vessel is occluded, the surgeon may make an anastomosis beyond the occlusion. Typically, the vessel that was occluded does not have any blood flowing through it. One prior art way to remedy this problem is to insert a stent in the area where the anastomosis is going to be placed. Unfortunately, the stent may occupy a large cross-sectional area of the vessel, reducing the overall flow through the vessel such that the area distal to the stent does not receive sufficient oxygenated blood.

This supplemental outflow port of the present invention eliminates the need for a stent and provides for a continuous source of oxygenated blood and therefore may reduce the post-surgical damage to the surrounding tissue after an anastomosis has been performed.

The present invention also concerns a supplemental inflow port for use with a blood pump.

The supplemental input port can be used to input blood from an area other than the main inflow region. For example, blood removed from the heart can be filtered and then introduced back into the patient
5 through the supplemental inflow port.

In one broad aspect of the present invention, an apparatus is provided comprising a blood pump, a main inflow port operably connected to the blood pump, a main outflow port operably connected to the blood
10 pump, and a supplemental port operably connected to the blood pump.

In one embodiment, the supplemental port is a supplemental outflow port.

In one embodiment, the supplemental outflow port
15 is connected to a catheter adapted to supply blood to perfuse a vein or artery.

In one embodiment, the supplemental outflow port is connected to a cannula adapted to be positioned in the patient's aorta.

20 In one embodiment, the supplemental port is a supplemental inflow port.

In one embodiment, the supplemental inflow port is connected to a catheter connected to a supply of blood.

25 In one embodiment, the supply of blood is connected to a catheter adapted to be positioned in the body to remove blood from the patient.

In one embodiment, the apparatus further comprises a valve at the supplemental port.

In one embodiment, the main inflow port is connected to a cannula adapted to be positioned in a
5 patient's atrium or ventricle.

In one embodiment, the main outflow port is connected to a cannula to be positioned in a patient's aorta.

In one embodiment, the main outflow port is
10 connected to a cannula to be positioned within a patient's artery.

In one embodiment, the blood pump is connected to an oxygenator.

In another broad aspect of the present
15 invention, an apparatus is provided comprising a blood pump including a main inflow port, a main outflow port, and a supplemental outflow port. The apparatus also includes a perfusion catheter connected to the supplemental outflow port, the
20 catheter adapted to supply blood to an artery on the heart during a bypass operation on that artery.

In a still further broad aspect of the present invention, a method is provided comprising the steps of: (a) operably connecting a blood pump to a
25 patient; (b) pumping blood from one part of the heart to another part of the heart; and (c) supplying blood through a supplemental port on the blood pump to an

DESCRIPTION OF THE PREFERRED EMBODIMENT

Illustrative embodiments of the invention are described below. In the interest of clarity, not all
5 features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers'
10 specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would
15 nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

The present invention is directed at providing an improved device and related methods for delivering
20 blood and/or other fluids to perfuse tissue and/or organs located downstream from a surgical site. Referring initially to FIG. 1, this is accomplished in one basic embodiment by equipping a pump 10 with a supplemental outflow port 12 in addition to the main
25 fluid inflow 14 and main fluid outflow 16 traditionally found in pumps. By way of example only, the pump 10 is presented as a centrifugal blood

009730-03400

pump well known in the art. The pump 10 normally operates under the direction of a motor (not shown) which drives an internally disposed impeller (not shown) so as to transport blood from the main fluid inflow port 14 in a generally tangential fashion out the main outflow port 16. In accordance with one embodiment of the present invention, the supplemental port 12 is formed on the structure defining the main fluid outflow port 16. As such, blood may be simultaneously directed through both the main outflow port 16 and the supplemental outflow port 12. As will be explained in greater detail below, when conducting an anastomosis or other surgical procedure that requires a supply of oxygenated blood, a cannula or catheter attached to the supplemental outflow port 12 may be employed to supply a pressurized flow of blood to (or downstream from) a surgical site.

Referring to FIG. 2, the pump 10 having the supplemental outflow port 12 according to the present invention is illustrated in use as part of a pump and cannula arrangement for providing left-heart assist. More specifically, an inflow cannula 20 is coupled to the main inflow port 14, an outflow cannula 22 is coupled to the main outflow port 16, and a perfusion catheter or cannula 24 is coupled to the supplemental outflow port 12. The inflow cannula 22 is dimensioned to extend through the wall of the left

atrium such that its distal end is disposed within the left ventricle. The outflow cannula 22 is dimensioned to extend through the wall of the aorta. Under the direction of the pump 10, blood may thus be withdrawn from the left ventricle and re-directed into the aorta, effectively bypassing the aortic valve, as may be required for various cardiac surgery procedures. In accordance with one embodiment of the present invention, the perfusion catheter 24 is dimensioned to extend into a blood vessel 30 on the exterior of the heart. More specifically, with combined reference to FIGS. 2 and 3, the perfusion catheter 24 is preferably to be positioned within the blood vessel 30 such that the distal end 26 extends past a damaged or diseased section 32 of the blood vessel 30, which is to be bypassed (such as via a coronary artery bypass graft (CABG) procedure), removed, or otherwise treated. In practice, the target vessel 30 will be occluded upstream of the damaged or diseased section 32, the occlusion being shown generically at 40.

According to the present invention, positioning the distal end 26 of the perfusion catheter 24 as shown provides the ability to deliver oxygenated blood within the vessel 30 to perfuse the heart tissue located downstream from the occlusion 40, such as while the surgeon is performing an anastomosis to

bypass the damaged or diseased section 32 in CABG procedures. In one embodiment, the distal end 26 of the perfusion catheter 24 may be equipped with a selectively inflatable balloon or similar occluding structure 28 designed to prevent the flow of blood upstream towards the damaged or diseased section 32. In this fashion, the balloon or occluding structure 28 helps to establish and maintain a bloodless field along a portion of the target blood vessel 30, thereby easing the challenge for the surgeon in performing the anastomosis.

Although shown as part of a left-heart bypass arrangement in FIG. 2, it is to be readily understood that the pump 10 having the supplemental port 12 of the present invention may be used in any number of cannulation arrangements for cardiac surgery. These may include (but are not necessarily limited to) pump and cannula arrangements for providing left-heart and/or right-heart support, such as set forth in U.S. Patent Application Serial Number 08/891,456 (assigned to the assignee of the present application and filed on July 11, 1997), the entire contents of which are hereby expressly incorporated herein by reference. When employed as part of a right-heart cannulation system, the pump 10 of the present invention would provide venous blood (withdrawn from the right side of the heart) through the supplemental port 12.

Although this venous blood is (by definition) oxygen depleted, this blood supply may nonetheless be helpful in perfusing locations downstream from a surgical site, as even oxygen-depleted blood is

5 better than no downstream blood flow at all.

Moreover, while blood pump 10 is shown as a generic centrifugal blood pump, it is to be readily understood that blood pump 10 may comprise any number of blood pumps, including but not limited to the

10 miniature centrifugal blood pump shown and described in U.S. Provisional Patent Application No. 60/178,479 (filed by the assignee of this application on January 26, 2000), the entire disclosure of which is hereby expressly incorporated herein by reference. It

15 should also be appreciated that, although shown and described above in use with the perfusion catheter 24 for tissue perfusion, the supplemental outflow port 12 may have a variety of other uses. These may include (but are not necessarily limited to) use as a

20 pressure tap to determine the pressure of the outflow from the pump 10, as well as for obtaining blood samples, such as for determining blood gas content.

Referring finally to FIG. 4, shown is an alternate embodiment of the present invention. The

25 blood pump 10 is provided with a supplemental inflow port 18 formed as part of the structure defining the main inflow port 14. Under the direction of the

009720" 274960

motor (not shown), the internally disposed impeller (not shown) will draw blood through the inflow cannula 20, through the pump 10, for delivery out a cannula (not shown) coupled to the main outflow port 5 16. In accordance with this aspect of the present invention, the supplemental inflow port 18 will provide the ability to draw another fluid into the pump 10 for delivery out the main outflow port 16. For example, during most surgical procedures, blood 10 is drained from the patient's chest cavity through the use of a suction device. Generally, this blood is deposited in a reservoir, such as at 40, via any suitable tubing or fluid conduit 42. The reservoir 40 may serve many purposes, such as for removing any 15 bubbles that develop in the blood during suction and/or filtering the blood 44 in order to recondition it for introduction back into the patient's blood supply. This filtering can be accomplished via any suitable mechanism, such as via the filter shown 20 generally at 46 near the bottom of the reservoir 40. As blood enters the reservoir 40, air will migrate towards the surface of the blood 44 and escape into the atmosphere. A return conduit 48 extends between the reservoir 40 and the supplemental inflow port 18 25 to allow the reconditioned blood 44 to be withdrawn into the blood supply being delivered into the pump 10. The reservoir 40 may be equipped with a flow

regulating mechanism (such as check-valve 50) to ensure that the return conduit 48 is occluded in the event the blood 44 within the reservoir 40 drops below a predetermined level.

5 The pump 10, equipped with the supplemental inflow port 18 according to the present invention, also advantageously allows the physician to infuse any of a variety of fluids into the blood stream of the patient. As well as the infusion of
10 reconditioned or recaptured blood as shown in FIG. 4, it may be necessary to infuse fluids or substances such as saline and/or various drugs into the patient. The supplemental inflow port 18 of the present invention also provides the ability to deliver these
15 fluids in large quantities and in quick fashion, which may be required in emergency situations where such actions must be taken to save the life of the patient.

As will be appreciated, other combination of the
20 various methods and elements can be used as appropriate. For example, the blood pump of the present invention may be coupled to an oxygenator. While the present invention has been described with reference to the aforementioned examples, this
25 description is not intended to be construed in a limiting sense. It should be readily understood that the components disclosed herein should all be made of

materials suitable for medical use, which materials are well known in the art. It should also be understood that all aspects of the present invention are not limited to the specific depictions, and that
5 relative proportions and sizing of the components may vary depending upon the particular situation or application.

Various modifications in form and detail of the embodiments shown herein will be apparent to skilled
10 artisans upon reference to this disclosure. It is therefore contemplated that all attendant claims shall cover any such modifications or variations of the described embodiments as following within the true spirit and scope of the present invention.

What is claimed is:

1. An apparatus, comprising:

a blood pump;

a main inflow port operably connected to the
blood pump;

a main outflow port operably connected to
the blood pump; and

a supplemental port operably connected to
the blood pump.

2. The apparatus of claim 1, wherein the
supplemental port is a supplemental outflow port.

3. The apparatus of claim 2, wherein the
supplemental outflow port is connected to a catheter
adapted to supply blood to perfuse a vein or artery.

4. The apparatus of claim 2, wherein the
supplemental outflow port is connected to a cannula
adapted to be positioned in the patient's aorta.

5. The apparatus of claim 1, wherein the
supplemental port is a supplemental inflow port.

6. The apparatus of claim 5, wherein the
supplemental inflow port is connected to a catheter
connected to a supply of blood.

7. The apparatus of claim 6, wherein the supply
of blood is connected to a catheter adapted to be
positioned in the body to remove blood from the
5 patient.

8. The apparatus of claim 1, further comprising
a valve at the supplemental port.

10 9. The apparatus of claim 1, wherein the main
inflow port is connected to a cannula adapted to be
positioned in a patient's atrium or ventricle.

10 10. The apparatus of claim 1, wherein the main
15 outflow port is connected to a cannula to be
positioned in a patient's aorta.

11. The apparatus of claim 1, wherein the main
outflow port is connected to a cannula to be
20 positioned within a patient's artery.

12. The apparatus of claim 1, wherein the blood
pump is connected to an oxygenator.

25 13. An apparatus, comprising:

a blood pump including a main inflow port,
a main outflow port, and a supplemental outflow
port; and

5 a perfusion catheter connected to the
supplemental outflow port, the catheter adapted
to supply blood to an artery on the heart during
a bypass operation on that artery.

14. A method, comprising the steps of:

- 10 (a) operably connecting a blood pump to a
patient;
(b) pumping blood from one part of the
heart to another part of the heart;
and
15 (c) supplying blood through a supplemental
port on the blood pump to an artery on
the heart during a bypass operation to
that artery.

20 15. The method of claim 14, wherein the blood
passes through an oxygenator.

16. The method of claim 14, wherein the blood
is supplied from the supplemental port to the artery
25 through a catheter.

17. The method of claim 14, wherein the blood is supplied from the supplemental port to the artery through a cannula.

5

ABSTRACT

A blood pump having a supplemental outflow port and/or a supplemental inflow port. A supplemental outflow port can be used to supply blood to regions
5 of the body during heart bypass operations, such as to perfuse heart tissue downstream from an anastomosis site during CABG procedures so as to reduce the damage to the heart tissue. A supplemental inflow port can be used to infuse blood
10 and/or various other fluids or compositions into the patient's blood stream, such as may be helpful or advantageous during emergency situations in cardiac surgery.

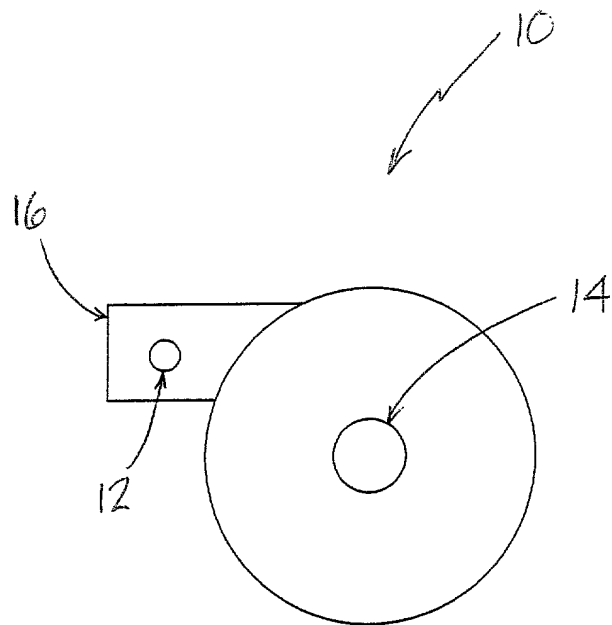


FIG. 1

Table 1. Demographic characteristics of the study population	
Age (years)	50.0 ± 10.0
Gender	
Male	50.0%
Female	50.0%
Marital status	
Married	50.0%
Single	50.0%
Divorced	50.0%
Widowed	50.0%
Education level	
High school or less	50.0%
College or more	50.0%
Occupation	
Professional	50.0%
Managerial	50.0%
Technical	50.0%
Service	50.0%
Unemployed	50.0%
Retired	50.0%
Health status	
Good	50.0%
Fair	50.0%
Poor	50.0%
Smoking status	
Smoker	50.0%
Non-smoker	50.0%
Alcohol consumption	
Regular	50.0%
Occasional	50.0%
Never	50.0%
Family size	
1-2	50.0%
3-4	50.0%
5 or more	50.0%
Income level	
Low	50.0%
Medium	50.0%
High	50.0%

FIG. 2

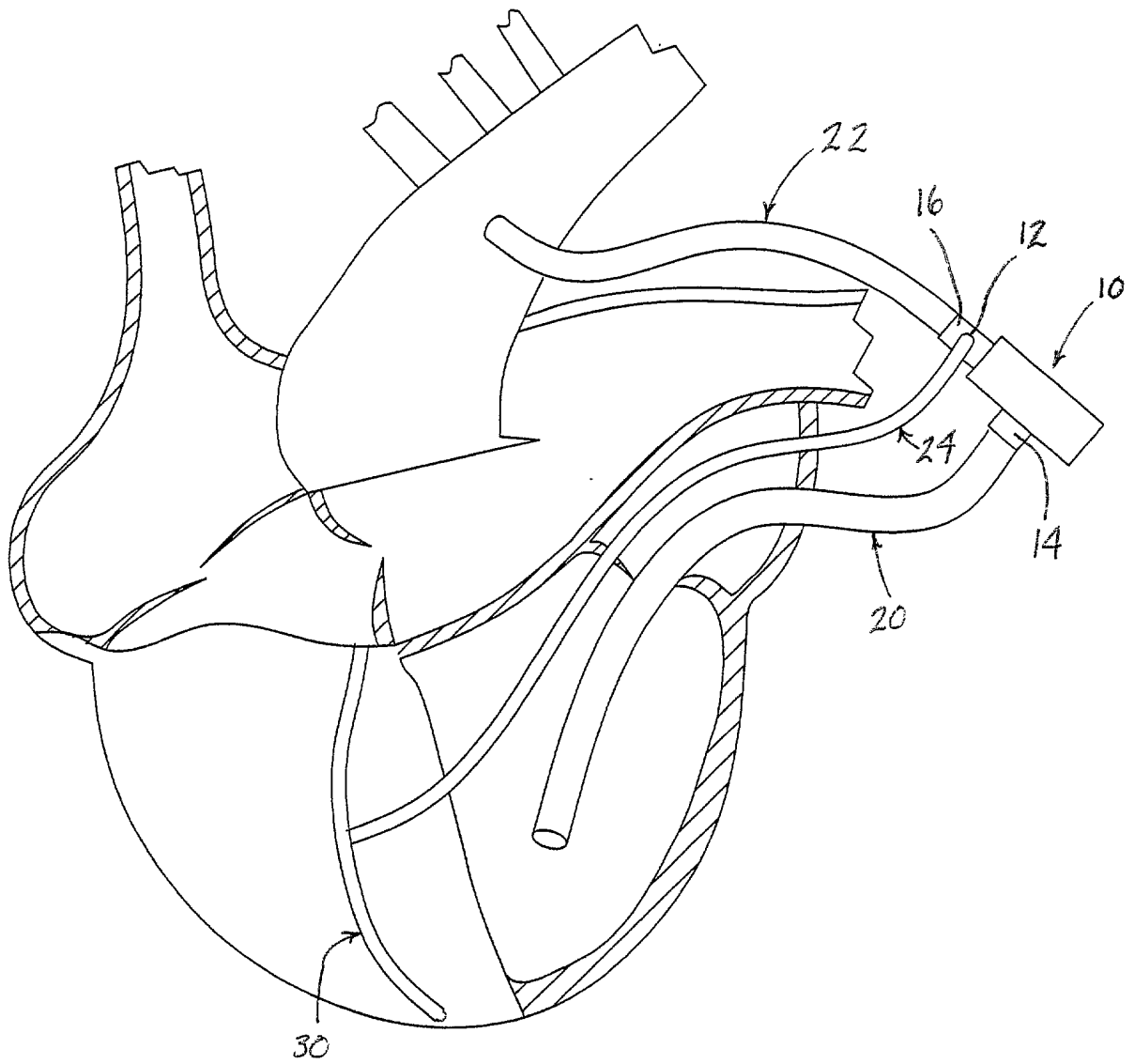
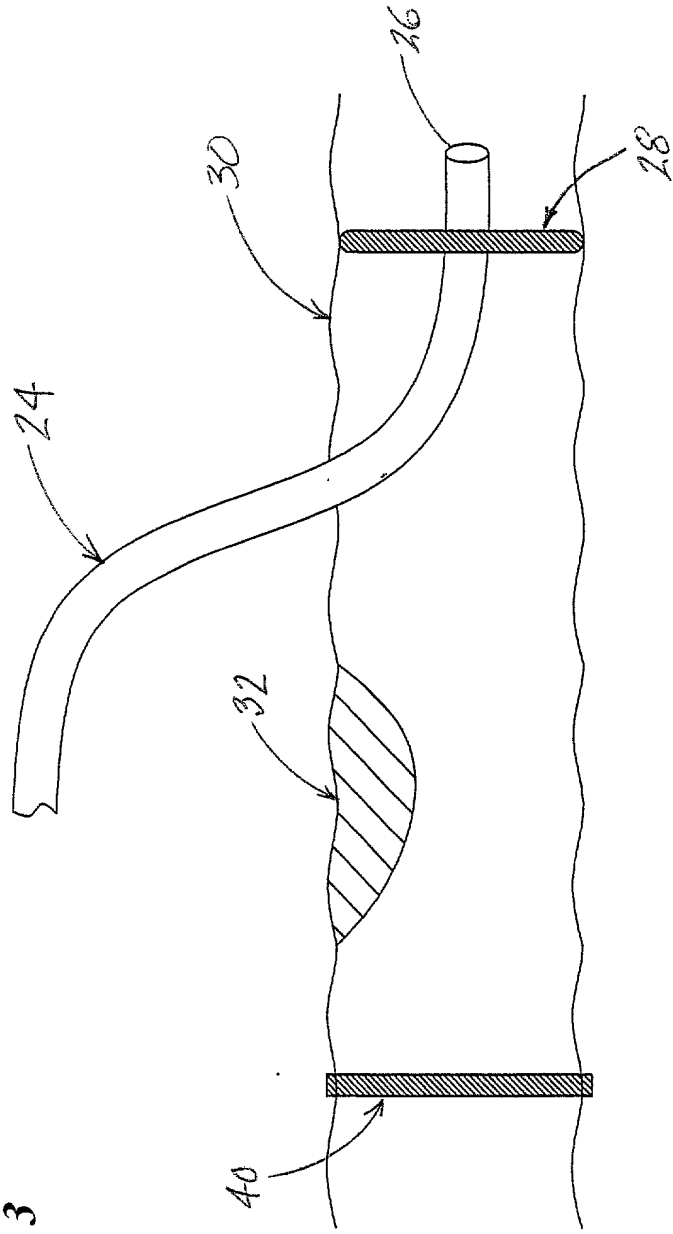


FIG. 3



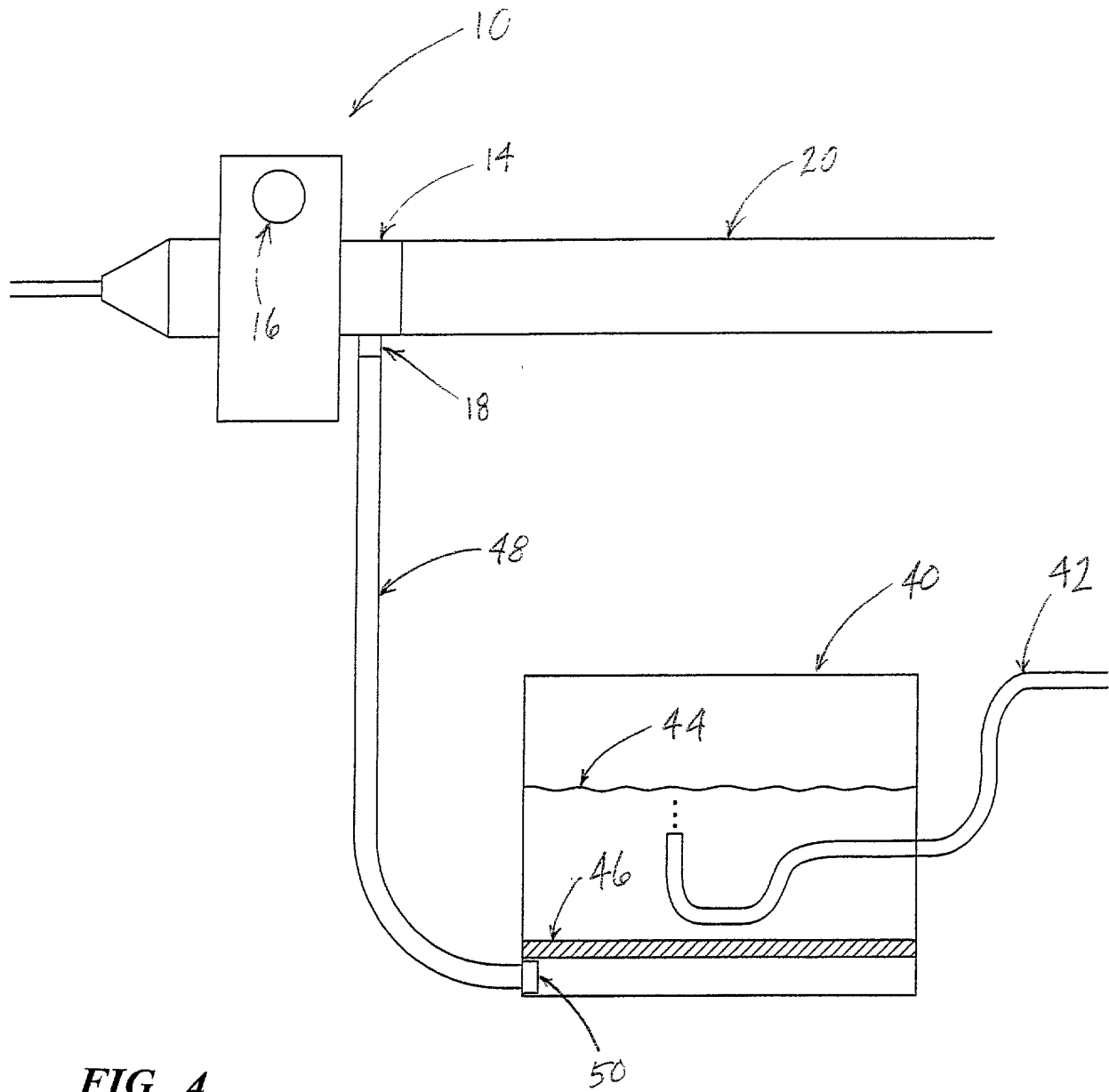


FIG. 4

Please type a plus sign (+) inside this box -> ☐

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)	Attorney Docket Number	PA036
	First Named Inventor	William Kanz
	<i>COMPLETE IF KNOWN</i>	
	Application Number	/
	Filing Date	August 16, 2000
	Group Art Unit	3762
<input checked="" type="checkbox"/> Declaration Submitted with Initial Filing	OR	<input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)
Examiner Name		Patricia Bianco

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"Supplemental Port for Catheter Perfusion of Surgical Site"

the specification of which (Title of the Invention)

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) [] as United States Application Number or PCT International

Application Number [] and was amended on (MM/DD/YYYY) [] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box --X



PTO/SB/01 (12-97)
Approved for use through 9/30/00. OMB 0651-0032

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application,

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
09/313,268	May 18, 1999	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith

☒ Customer Number 23710

OR

☐ Registered practitioner(s) name/registration number listed below

Place Customer Number Bar Code Label here

Name	Registration Number	Name	Registration Number
Jonathan Spangler, Esq.	40,182		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 23710 OR ☐ Correspondence address below

Name					
Address	A-Med Systems, Inc.				
Address	2491 Boatman Avenue				
City	West Sacramento	State	California	ZIP	95691
Country	US	Telephone	(916) 375-7400, Ext. 301	Fax	(916) 375-7444

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle if any)		Family Name or Surname			
William Russell		Kanz			
Inventor's Signature				Date	8/14/00
Residence: City	Sacramento	State	California	Country	US
Post Office Address	4695 Francis Court				
Post Office Address					
City	Sacramento	State	California	ZIP	95822
		Country	US		

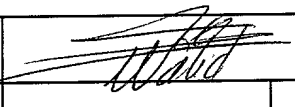
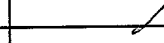
☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached here

Please type a plus sign (+) inside this box → ☒Approved for use through 9/30/98 OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 3 of 3

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Walid Najib				Aboul-Hosn			
Inventor's Signature						Date	
Residence: City	Fair Oaks	State	California	Country	US	Citizenship	US
Post Office Address	4625 Chicago Avenue						
Post Office Address							
City	Fair Oaks	State	California	ZIP	94628	Country	US
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231 DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

0944403-004600